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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/628,692 | 07/28/2003 | Brent L. Atkinson | CRM-P15F/P | 5172 |
| 7590 12/11/2008 DENTSPLY INTERNATIONAL INC. 570 West College Avenue York, PA 18405-0872 | | | | |
| EXAMINER BRADLEY, CHRISTINA | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,692

Applicant(s)

ATKINSON ET AL.

Examiner

Christina Marchetti Bradley

Art Unit

1654

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 12-14 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 12-14 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 1-8, 10, 12-14 and 19 are pending; claims 9 and 11 were cancelled in the amendment filed 08/27/2008.

Claim Rejections - 35 USC § 102

2. The rejection of claims 1, 4, 5, 8 and 10 under 35 U.S.C. 102(b) as being anticipated by Gertzman *et al.* (U.S. Patent No. 6,030,645) is withdrawn in light of the amendment filed 08/27/2008.
3. The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Ewers *et al.* (U.S. Patent No. 6,428,803) is withdrawn in light of the amendment filed 08/27/2008.
4. The rejection of claims 1, 4 and 12 under 35 U.S.C. 102(a) and 102(e) as being anticipated by Peterson *et al.* (US 2002/0071827) is withdrawn in light of the amendment filed 08/27/2008.

Claim Rejections - 35 USC § 103

5. The rejection of claims 1, 4-6 and 8-11 under 35 U.S.C. 103(a) as being unpatentable over Gertzman *et al.* (U.S. Patent No. 6,030,635) is withdrawn in light of the amendment filed 08/27/2008.
6. The rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over Gertzman *et al.* (U.S. Patent No. 6,030,635) and Tofe (US 2003/0143283) is withdrawn in light of the amendment filed 08/27/2008.

7. The rejection of claim under 35 U.S.C. 103(a) as being unpatentable over Gertzman *et al.* (U.S. Patent No. 6,030,635) and Ewers *et al.* (U.S. Patent No. 4,770,860) is withdrawn in light of the amendment filed 08/27/2008.
8. The rejection of claim 12 under 35 U.S.C. 103(a) as being unpatentable over Gertzman *et al.* (U.S. Patent No. 6,030,635) and Peterson *et al.* (US 2002/0071827) is withdrawn in light of the amendment filed 08/27/2008.
9. The rejection of claims 7, 13, 14 and 19 under 35 U.S.C. 103(a) as being unpatentable over Gertzman *et al.* (U.S. Patent No. 6,030,635) and Bhatnager (U.S. Patent No. 5,635,482) is withdrawn in light of the amendment filed 08/27/2008.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-8, 10, 12-14 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
12. The claims are drawn to a bone putty material comprising 1) 55 weight percent or greater of a porous, resorbable particulate derived of anorganic bone mineral or natural bone-derived material or synthetic hydroxyapatite with a bulk density of 1.1 to 1.3 g/cc; and 2) a resorbable carrier gel component for suspending said particulate, forming a putty-like formulation. The

bone putty material may also comprise a P-15 polypeptide sequence or synthetic biomimetic bound to the particulate or to xenogenic bone mineral particulate.

13. A single embodiment of the claimed invention was actually reduced to practice at the time of filing. The specification discloses a bone putty composition comprising 55 weight percent PEPGEN P-15 (OsteoGraf®/N 300), the bulk density of which is 1.2 g/cc (p. 18). To prepare this composition 55 grams of PEPGEN P-15® bone graft material supplied by Dentsply Friadent CeraMed of Lakewood, Colorado, comprising a P-15 poly peptide sequence described by Bhatnagar in US 5,635,482, irreversibly bound to a natural microporous, xenogenic bone material OsteoGraf®/N 300, was weighed out into a container. A hyaluronic acid gel was prepared by blending 92% sodium phosphate buffer with 8% hyaluronate by weight (molecular weight $1.2-1.7 \times 10^6$ Daltons) to homogeneity. 45 grams of hyaluronic acid gel was mixed with the PEPGEN P-15 material by means of a spatula to homogeneity. The resulting material is of a moldable, putty-like consistency and deemed to have the most preferred handling characteristics of the samples tested. (Examples 1, 4 and 7)

14. The specification fails to disclose any additional bone repair putty materials that meet the claim limitations of 55 weight percent of greater of a particulate having a bulk density 1.1 to 1.3 g/cc. The specification does not provide any guidance as to how to identify other suitable particulate/carrier combinations. Of the seven example on p. 18, only the PEPGEN P-15/HA combination meets the weight percent and bulk density of the instant claims as currently amended.

15. The description of the preferred bone repair putty composition in Examples 1, 4 and 7 and on page 18 of the specification utilizes the trademark or trade names PEPGEN P-15 and

OsteoGraf®/N 300. MPEP § 2173.05 states that a trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the instant case, the composition and physical properties of PEPGEN P-15 and OsteoGraf®/N 300 are not fully described in generic terminology.

16. Thus, when the above factors are weighed, one of ordinary skill in the art would not recognize that Applicant was in possession of the claimed bone repair putty at the time of filing.

Conclusion

17. No claims are allowed.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Marchetti Bradley whose telephone number is (571)272-9044. The examiner can normally be reached on Monday-Thursday, 9:00 A.M. to 3:00 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 1654

/Christina Marchetti Bradley/
Examiner, Art Unit 1654